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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030

7590 08/25/2005

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,815	AOMATSU, AKIRA	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/27/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-33* is/are pending in the application.

4a) Of the above claim(s) *32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _.

DETAILED ACTION

Status of Application

1. By Amendment filed May 27, 2005, claims 25 and 29-30 have been amended and claim 33 has been newly added. Claims 25-31 and 33 are currently pending for prosecution on the merits.

2. Applicant's arguments with respect to claims 25-31 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment (which requires "for stabilizing the composition" and "auxiliary agent which is different than water" in claims 25-31 and "further comprising water" in claim 33) necessitates a new ground of rejection(s) in this Office Action.

Claim Objections

3. Claim 25 is objected to because of the following informalities: Improper Markush-Type of language is used in claim 25. It is suggested to amend "selected from gabapentin or pregabalin" to "selected from the group consisting of gabapentin and pregabalin".

New Matter

4. The amendment filed May 27, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "auxiliary agent which is different than water".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims in this application introduce new limitation as discussed in preceding comments, namely "auxiliary agent which is different than water". The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification.

The specification discloses that if necessary auxiliary agent is utilized in formulating pharmaceutical preparation (see for example p. 13, line 23 and p. 36, line 19-20). Although it is not specific, the specification discloses water as agent utilized in preparing pharmaceutical preparation (see for example p. 39, lines 29-32, p. 42, line 20-21 and Examples). Therefore, it would have been clear to one skilled in the art, reading the instant disclosure, that the claimed invention can be practiced with water. As stated above, the specification only positively states about the boundaries of the claim. There is no express statement about the negative limitation that can be found in the specification. Thus, the exclusion of said elements implies the inclusion

of all other elements not expressly excluded, clearly illustrating that such negative limitations do, in fact, introduce new matter. The negative limitation recited in the present claims, which did not appear in the specification filed, introduces new concepts and violate the description requirement of the first paragraph of 35 USC 112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25-27, 29 and 31 are rejected under 35 USC 102(b) as being anticipated by Woodruff (US 5084479).

The amended claims now requires "auxiliary agent which is different than water".

Woodruff discloses a solution comprising N-methyl-D-aspartic acid and gabapentin with presence of TTX (column 8, lines 4-14).

Since the interpretation of said auxiliary agent (The American Heritage Dictionary, Second College Edition, 1982 defines "auxiliary" as "giving assistance or support; helping; acting as a subsidiary; supplementary) allows for inclusion of any secondary ingredients, the referenced composition comprising N-methyl-D-aspartic acid and gabapentin with presence of TTX anticipates the claimed composition. Furthermore, since the interpretation of the instant claims does not totally exclude the use of water in said composition (see for example new claim

33), the referenced final solution containing N-methyl-D-aspratic acid, gabapentin and water, with the presence of TTX, anticipates the claimed invention.

Although the reference is silent about the functional characteristic of alpha amino acid as stabilizing agent, such recitations of inherent property or characteristic is not limited to the interpretation of composition claim since there is no specific dosage amounts of alpha amino acid recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 25-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robson et al. (US 4126684) in view of Costa et al. (US 5248678).

Robson discloses a composition comprising baclofen, alpha amino acid such as glycine, auxiliary agent (i.e., mannitol, lactose, etc...) and aqeous gelatin solution. See Example 2.

Costa is being supplied as the reference to demonstrate the art recognized functional equivalent of gabapentin, baclofen, vigabatrin and muscimol as GABA agonists.

The teaching of Seiler differs from the claimed invention (i) in the combination use of gabapentin and glycine in a composition and (ii) the specific amount of alpha-amino acid (e.g., glycine) in said composition. To incorporate such teaching into the teaching of Seiler, would have been obvious in view of Costa who teaches or suggests the use of gabapentin as functional equivalent of baclofen as a GABA agonist.

It would have been obvious to make the gabapentin and glycine combination since the examiner takes Official Notice of the equivalence of gabapentin and baclofen as GABA agonist in the art and the selection of any of known GABA agonists from limited examples of Costa to form the claimed combination with the GABA agonist would be within the level of ordinary skill in the art.

As discussed above, examiner takes Official Notice the fact that gabapentin is known in the pharmaceutical art to be equivalent to baclofen as GABA agonist. To substitute gabapentin for the disclosed baclofen would have been an obvious functional equivalent

In addition, optimization of amounts of known active and/or inactive ingredients in a composition or determination of the specific delivery dosage form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 25-31 and 33 are rejected under the judicially created doctrine of double patenting over claims 28-39 of Copending US Application No. 09/674,819.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed composition is overlapping with the claimed scope of the copending application. Since the interpretation of the instant claim allows for the inclusion of any other unspecified ingredients even in major amounts in said composition, the presence of humectant in said composition in the copending application makes obvious the instant claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No Claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon